ADVANCED ANTACID MINT- aluminum hydroxide, magnesium hydroxide, dimethicone suspension GOODSENSE

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

GS ant mnt

Active ingredients (in each 10 mL dose)

Aluminum hydroxide 400 mg (equivalent to dried gel, USP)

Magnesium hydroxide 400 mg

Simethicone 40mg

Purposes

Antacid

Antigas

Uses

relieves

- heartburn
- sour stomach
- acid indigestion
- the symptoms referred to as gas

Warnings

Ask a doctor before use if you have

- · kidney disease
- a magnesium-restricted diet

Ask a doctor or pharmacist before use if you are taking a prescription drug.

Antacids may interact with certain prescription drugs.

Stop use and ask a doctor if symptoms last more than 2 weeks

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children.

Directions

- shake well before each use
- adults and children 12 years and older: take 10 mL to 20 mL (1-2 doses) four times a day or as directed by a doctor
- do not exceed 80 mL (8 doses) in a 24 hour period or use the

maximum dosage for more than 2 weeks

• children under 12 years: ask a doctor

Other information

- each 10 mL dose contains: magnesium 165 mg, sodium 6 mg
- store at room temperature
- protect from freezing
- keep tightly closed

Inactive ingredients

benzyl alcohol, butylparaben, carboxymethylcellulose sodium, flavor, hypromellose, microcrystalline cellulose, propylparaben, purified water, saccharin sodium, sorbitol solution

package Label



aluminum hydroxide, magnesium hydroxide, dimethicone suspension

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50804-639
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ALUMINUM HYDRO XIDE (UNII: 5QB0T2IUN0) (ALUMINUM HYDRO XIDE - UNII:5QB0T2IUN0)	ALUMINUM HYDRO XIDE	400 mg in 10 mL	
MAGNESIUM HYDRO XIDE (UNII: NBZ3QY004S) (MAGNESIUM CATION - UNII:T6 V3LHY838, HYDRO XIDE ION - UNII:9159 UV381P)	MAGNESIUM HYDRO XIDE	400 mg in 10 mL	
DIMETHICO NE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	40 mg in 10 mL	

Inactive Ingredients			
Ingredient Name	Strength		
BENZYL ALCOHOL (UNII: LKG8494WBH)			
BUTYLPARABEN (UNII: 3QPI1U3FV8)			
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679 OBS 311)			
HYPROMELLOSES (UNII: 3NXW29V3WO)			
CELLULO SE, MICRO CRYSTALLINE (UNII: OP1R32D61U)			
PROPYLPARABEN (UNII: Z8IX2SC1OH)			
WATER (UNII: 059QF0KO0R)			
SACCHARIN SO DIUM (UNII: SB8 ZUX40 TY)			
SORBITOL (UNII: 506T60A25R)			

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

Packaging					
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:50804-639-12	355 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2020	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part331	07/01/2020		

Labeler - GOODSENSE (076059836)

Registrant - GCP Laboratories (965480861)

Establishment				
Name	Address	ID/FEI	Business Operations	
GCP Laboratories		965480861	manufacture(50804-639)	

Revised: 9/2020 GOODSENSE